EXHIBIT K

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Miami Field Office

Appeal of:	**Parrish Law Firm on behalf of A. Prosser**	ALJ Appeal No.:	**1-8380637906**
Beneficiary:	**Anniken Prosser**	**Medicare Part B**	
HICN:	*****4857A**	Before:	**Lissette M. Figueroa** U.S. Administrative Law Judge

DECISION

After carefully considering the evidence and arguments presented in the record and at the hearing, a **FAVORABLE** decision is entered in the appeal of A. Prosser. (Appellant).

Procedural History

Novocure submitted claims to Medicare for an E0766 (electrical stimulation device used cancer treatment) for the dates of services of May 16, 2018, June 16, 2018, and July 16, 2018. The claims were initially denied on May 23, 2018, because Medicare guidelines were not met. Redetermination request was made to CGS, the Medicare Contractor with jurisdiction. On September 27, 2018, 2018, CGS concluded the following:

> Medicare does not cover tumor treatment field therapy (E0766) or therapy supplies (A4555) as the currently published studies in the medical literature do not clearly document the effectiveness of this device per LCD L34823. (Exhibit 1, pages 21-23).

On January 22, 2019, the Parrish Law Firm informed the Qualified Independent Contractor (QIC); it was representing Ms. Prosser and requested a reconsideration of the previous denial. On March 15, 2019, the QIC affirmed the Plan. (Exhibit 1, pages 1-13).

The QIC completed a review of the Manuals; peer review language submitted by the Appellant, and the LCD, yet still determined the requested service was denied as not reasonable and necessary. The QIC did acknowledge that DME MACs have found a "request for newly diagnosed glioblastoma as valid; however the DMEs have bot issued a new LCD providing coverage for newly diagnosed glioblastoma." (Exhibit 1, pages 9-10).

On March 21, 2019, the Office of Medicare Hearings and Appeals (OMHA) received the Appellant's timely Request for Medicare Hearing by an Administrative Law Judge (ALJ) from the Beneficiary's representative. (Exhibit 3, pages 1-4). The remaining amount in controversy meets the jurisdictional

requirements for a hearing before OMHA.[1] Therefore, the jurisdictional predicates are met and the claim for ambulance services, which is covered by this decision, is properly before the ALJ for *de novo* review.

Ms. Parrish submitted additional items (peer review literature, LCD, and prior ALJ decisions) with the Request for Hearing and same were admitted into the record as Exhibit 5 and Exhibit 6.

On May 28, 2019, the undersigned conducted a telephone hearing from the OMHA Miami Field Office. The QIC was provided with a notice of hearing, but did not attend. Attendees at the hearing included: Bridget Noonan, Esq. as Counsel for the Beneficiary and Mr. Timothy Parks on behalf of Novocure. Subsequent to the hearing, Ms. Parrish submitted the proposed LCD for newly diagnosed glioblastomas and this was admitted into the record as Exhibit 7.

Issues

1) The appeal presents the following issue: Is the appellant entitled to Medicare reimbursement under Part B of Title XVIII of the Social Security Act (the Act) for the tumor treatment field therapy furnished to the appellant on the dates of service of May 16, 2018, June 16, 2018, and July 16, 2018? In other words, are such services within a covered category under 1861(s)(3) of the Act, and if so, are such services not otherwise excluded from coverage under §1862(a)(1) of the Act?

2) Whether payment can otherwise be made to the Appellant pursuant to the waiver of liability provisions under Section 1879 of the Act and 42 C.F.R. § 411.406, if it is determined that the item was not medically reasonable and necessary under Section 1862 (a)(1) of the Act.

Findings of Fact

1. Physician progress note dated February 16, 2017, described the Beneficiary as a 33-year-old female that presented to her physician for follow-up evaluation and management of a left temporal Grade 4 astrocytoma[2]. Neuro-oncology exam revealed the following: 1) a history of migraines which started in her 20's possibly secondary to Crohn's medication; 2) intractable migraine on February 14, 2016, and MRI which showed a left cystic temporal mass; 3) left craniotomy- GBM on February 25, 2016; 4) completed radiation with concurrent temodar; 5) adjuvant temodar; and

[1] 67 Fed. Reg. 62478 (October 7, 2002) and 70 Fed. Reg. 11423 (March 8, 2005)

[2] Grade IV astrocytoma is also called glioblastoma or GBM and is the most aggressive type of nervous system tumor. It is also referred to as glioblastoma multiforme because of its wide variety of appearances under the microscope. Rarely, non-glial tissue elements can exist in a glioblastoma. The most common variant of GBM showing these additional tissue elements is called a mixed glioblastoma-sarcoma, or gliosarcoma. GBM occurs most often in adults between the ages of 50 and 80, is more common in men, and accounts for 23% of all primary brain tumors. Grade IV astrocytoma: The three main forms of treatment for GBM are surgery and radiation or chemotherapy. These treatments may be used alone or in combination with one another. The initial treatment in most cases is surgical excision and removal of as much as the tumor as possible (resection). Often, only a portion of the tumor can be safely removed because malignant cells may have spread to surrounding brain tissue. Because surgery cannot completely remove a tumor, radiation therapy and chemotherapy are used following surgery to continue treatment.

The FDA has approved Temozolomide (Temodar) for the treatment of adults with GBM. Temozolomide is used concurrently with radiation therapy, and for a period after completion of radiotherapy. For more information, contact:

https://rarediseases.org/rare-diseases/astrocytoma/

6) start of Optune TTFields. (Exhibit 2, page 34). Past medical history included Crohn's disease, and Wolff-Parkinson-White Syndrome[3] (1999). Physician's plan included a continuation of Optune TTFields, adjuvant temodar, and RTC 2 months with MRI. (Exhibit 2, page 37).

2. Physician progress note dated March 15, 2018, showed the Beneficiary presented for follow-up. The physician indicated the Beneficiary was neurologically intact and radiographically stable and was tolerating TTFields. Recommendation was to continue Optune TTFields and RTC 3 months with MRI. (Exhibit 2, pages 1-4).

3. Optune Prescription Form dated April 13, 2018, indicated the physician ordered a 6-month prescription for the Beneficiary due to glioblastoma multiforme. (Exhibit 2, pages 41-42).

4. The Beneficiary signed Optune Service Agreement and delivery confirmation on May 19, 2016. (Exhibit 1, pages 44-63A).

5. Invoices from Novocure were submitted to Medicare for dates of service: May 16, 2018, June 16, 2018, and July 16, 2018. (Exhibit 2, pages 39-41).

6. The Parrish Law Firm submitted literature and Professional Studies. (See Exhibit 5).

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

Individuals or organizations dissatisfied with the reconsideration of an initial determination are entitled to a hearing before the Secretary of the Department of Health and Human Services (HHS) provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Act § 1869(b)(1)(A).

In implementing this statutory directive, the Secretary has delegated the authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. 70 Fed. Reg. 36386, 36387 (June 23, 2005). The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council. *Id.*

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[3] In Wolff-Parkinson-White (WPW) syndrome, an extra electrical pathway between your heart's upper and lower chambers causes a rapid heartbeat. The extra pathway is present at birth and rare.

The episodes of fast heartbeats usually are not life threatening, but serious heart problems can occur. Treatment can stop or prevent episodes of fast heartbeats. A catheter-based procedure (ablation) can permanently correct the heart rhythm problems. Most people with an extra electrical pathway experience no fast heartbeat. This condition, called Wolff-Parkinson-White pattern, is discovered only by chance during a heart exam. Although WPW pattern is often harmless, doctors might recommend further evaluation before children with WPW pattern participate in high-intensity sports. https://www.mayoclinic.org/diseases-conditions/wolff-parkinson-white-syndrome/symptoms-causes/syc-20354626

For requests filed on or after January 1, 2018, the AIC threshold for requests for Administrative Law Judge hearings will remain at $160, and the AIC threshold for seeking judicial review will increase to $1,600. The notice is available at https://www.gpo.gov/fdsys/pkg/FR-2017-09-29/pdf/2017-20883.pdf.

B. Scope of Review

For all appeals stemming from a QIC, the ALJ appeals process is governed by 42 C.F.R. §§ 405.1000 *et seq.* 42 C.F.R. § 405.1032 states, "[t]he issues before the administrative law judge include all the issues brought out in the initial, reconsidered, or revised determination that were not decided entirely in your favor. However, if evidence presented before or during the hearing causes the administrative law judge to question a fully favorable determination, he or she will notify you and will consider it an issue at the hearing."

C. Standard of Review

The ALJ conducts a de novo review of each claim at issue and issues a decision based on the hearing record. 42 C.F.R. § 405.1000(d) and Section 557 of the Administrative Procedure Act. A de novo review requires the ALJ to review and evaluate the evidence without regard to the findings in the prior determinations on the claim and make an independent assessment in reliance upon the evidence and controlling laws. All laws and regulations pertaining to the Medicare and Medicaid programs, including, but not limited to Titles XI, XVIII, and XIX of the Social Security Act and applicable implementing regulations, are binding on ALJ's. 42 CFR § 405.1063. The burden of proving each element of a Medicare claim lies with the Appellant and is by preponderance of the evidence (i.e. satisfied through the submission of sufficient evidence in accordance with Medicare rules). See e.g., Sections 1814(a)(1), 1815(b), and 1833(e) of the Act; see also 42 C.F.R. § 424.5(a)(6), 42 C.F.R. § 405.1018, 42 C.F.R. § 405.1028, and 42 C.F.R. § 405.1030.

II. Principles of Law

A. *Statutes and Regulations*

Section 1831 of the Act establishes a supplementary insurance program for the aged and disabled. This insurance program, commonly referred to as Part B of Medicare, is financed through premium payments by enrollees together with contributions from funds appropriated by the Federal Government. §1831; *42 U.S.C. 1395j.* The program allows for the reimbursement of physicians' services including surgery, consultation, and office visits. §1861(q); *42 U.S.C. 1395x(q)*

The standard for payment of these services is found in section 1862(a)(1)(A) of the Act. There, the Act states that no payment may be made "...for items and services...[which] are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

Section 1833(e) of the Act provides that payment will not be made unless sufficient information is furnished to determine the amounts due to the provider. *See also* 42 CFR §424.5(6).

Section 1862(a)(1)(A) of the Act provides that "[n]otwithstanding any other provision of the Act, no payment shall be made for any expenses incurred for items and services that are not reasonable and

necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." *See also* 42 C.F.R. §411.15(k).

Section 1862(a)(12) of the Act provides that no payment may be made for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, except that payment may be made under part A in the case of inpatient hospital services in connection with the provision of such dental services if the individual, because of his underlying medical condition and clinical status or because of the severity of the dental procedure, requires hospitalization in connection with the provision of such services.

Section 1866(a)(1)(A)(i) of the Act provides that "[a]ny provider of services (except a fund designated for purposes of section 1814(g) and section 1835(e)) shall be qualified to participate under this title and shall be eligible for payments under this title if it files with the Secretary an agreement not to charge, except as provided in paragraph (2), any individual or any other person for items or services for which such individual is entitled to have payment made under this title (or for which he would be so entitled if such provider of services had complied with the procedural and other requirements under or pursuant to this title or for which such provider is paid pursuant to the provisions of section 1814(e)) of the Act." *See also* 42 C.F.R. §489.1 *et seq.* (setting forth the terms and limitations on provider agreements).

Section 1879 of the Act limits the liability of the Beneficiary and providers of services if the services are found to be not medically reasonable and necessary under Section 1862(a)(1)(A) or care was custodial in nature under Section 1862(a)(9) of the Act. Payment will only be made pursuant to this section if neither the Beneficiary nor the provider knew or could reasonably have been expected to know that the services were not covered. *See also* 42 C.F.R. §411.404; 42 C.F.R. §411.406.

B. Policy and Guidance

Section 1871(a)(2) of the Act states that unless promulgated as a regulation by CMS, no rule, requirement, or statement of policy, other than a National Coverage Determination (NCD), can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program. However, in lieu of binding regulations with the full force and effect of law, CMS and its contractors have issued policy guidance that describe criteria for coverage of selected types of medical items and services in the form of manuals and local medical review policies (LMRPs) or local coverage determinations (LCDs).

Section 1869(f)(1) of the Act provides that NCDs are binding upon Administrative Law Judges. *See also* 42 CFR §405.1060. *Medicare National Coverage Determinations Manual, Pub. 100-03, Ch. 1, sec. 280* ("NCD 280.1") provides a mandatory statement as to what constitutes equipment that the meets the definition of DME, as follows:

"The term DME is defined as equipment which:

* Can withstand repeated use; i.e., could normally be rented and used by successive patients;
* **Is primarily and customarily used to serve a medical purpose**;
* Generally is not useful to a person in the absence of illness or injury; and,

* Is appropriate for use in a patient's home."

Section §1869(f)(2) of the Act provides that Administrative Law Judges will give substantial deference to LCDs, LMRPs, or CMS program guidance when applicable, and if they do not follow the policy they must explain why in their decision. *See also* 42 CFR §405.1062. The Local Coverage Determination Policy applicable to this case. The LCD at issue is L34823 and Policy Article 52711.

L34823

In addition to the "reasonable and necessary" criteria contained in this LCD, there are other payment rules, which are discussed in the following documents that must also be met prior to Medicare reimbursement:

- The LCD-related Standard Documentation Requirements Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- The LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.

- Refer to the Supplier Manual for additional information on documentation requirements.
- Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

For the items addressed in this LCD, the "reasonable and necessary" criteria, based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.

GENERAL

A Detailed Written Order (DWO) (if applicable) must be received by the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving a completed DWO, the claim shall be denied as not reasonable and necessary.

An item/service is correctly coded when it meets all the coding guidelines listed in CMS HCPCS guidelines, LCDs, LCD-related Policy Articles, or DME MAC articles. Claims that do not meet coding guidelines shall be denied as not reasonable and necessary/incorrectly coded.

Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files. Proof of delivery documentation must be made available to the Medicare contractor

Policy Article 52711

Code E0766 describes devices that generate electromagnetic fields utilized in the treatment of cancer. The electromagnetic energy generated is transmitted to the body by means of surface

electrodes or transducers.

This code is inclusive of all associated supplies necessary for the effective use of code E0766 including, but not limited to, transducers/surface electrodes, lead wires, adhesive patches, connectors, conductive gel and skin preps.

Proposed changes to LCD DL34823

On May 9, 2019, The Centers for Medicare and Medicaid Services (CMS) assigned to the Durable Medical Equipment Medicare Administrative Contractors (DME MACs) the task of developing Local Coverage Determinations (LCDs) for Durable Medical Equipment, Prostheses, Orthoses, and Supplies (DMEPOS). The DME MACs are proposing a revision to the **Tumor Treatment Field Therapy (TTFT LCD L34823)** to cover newly diagnosed glioblastoma multiforme (GBM).

The proposed policy extends coverage for use of TTFT as a treatment option for Medicare beneficiaries with newly diagnosed GBM when certain coverage criteria are met. Stakeholders may read the details of the proposed TTFT LCD posted on the Medicare Coverage Database (Reference DME MAC DL34823). The entire LCD should be completely reviewed prior to the submission of written comments.

Medicare Benefit Policy Manual, Pub. 100-02 ("CMS Pub. 100-02"), Ch. 15, §110.1, also provides guidance pertaining to Medicare coverage of DME, and explains that

> Expenses incurred by a beneficiary for the rental or purchases of durable medical equipment (DME) are reimbursable if the following three requirements are met:

- The equipment meets the definition of DME (§110.1);
- The equipment is necessary and reasonable for the treatment of the patient's illness or injury or to improve the functioning of his or her malformed body member (§110.1); and
- The equipment is used in the patient's home.

Ch. 15, §110.1(A) further explains as follows:

- Equipment, which is primarily and customarily used for a nonmedical purpose, may not be considered "medical" equipment for which payment can be made under the medical insurance program. This is true even though the item has some remote medically related use. For example, in the case of a cardiac patient, an air conditioner might possibly be used to lower room temperature to reduce fluid loss in the patient and to restore an environment conducive to maintenance of the proper fluid balance. Nevertheless, because the primary and customary use of an air conditioner is a nonmedical one, the air conditioner cannot be deemed medical equipment for which payment can be made.

- Other devices and equipment used for environmental control or to enhance the environmental setting in which the beneficiary is placed are not considered covered DME. These include, for example, room heaters, humidifiers, dehumidifiers, and electric air cleaners. Equipment, which serves comfort or convenience, functions or is primarily for the convenience of a person caring for the patient, such as elevators, stairway elevators, and posture chairs, do not constitute medical equipment. Similarly, physical fitness

equipment (such as an exercycle), first-aid **or precautionary-type equipment (such as preset portable oxygen units)**, self-help devices (such as safety grab bars), and training equipment (such as Braille training texts) **are considered nonmedical in nature**.

Medicare Program Integrity Manual, Pub. 100-08, ("CMS Pub. 100-08"), Ch. 5, provides guidance as to documentation for DME claims, including the requirement of both physician orders for DME and supporting documentation for medical necessity and delivery. *Ch. 5,* also provides guidance as to patient documentation requirements to support that Medicare coverage criteria for items of DME have been met.

> For any DMEPOS [Durable Medical Equipment Prosthetics Orthotics and Supplies] item to be covered by Medicare, the patient's medical record must contain sufficient documentation of the patient's medical condition to substantiate the necessity for the type and quantity of items ordered and for the frequency of use or replacement (if applicable). The information should include the patient's diagnosis and other pertinent information including, but not limited to, duration of the patient's condition, clinical course (worsening or improvement), prognosis, nature and extent of functional limitations, other therapeutic interventions and results, past experience with related items, etc. . . . neither a physician's order nor a CMN [certificate of medical necessity] . . . nor a supplier prepared statement nor a physician attestation by itself provides sufficient documentation of medical necessity, even though it is signed by the treating physician or supplier. There must be information in the patient's medical record that supports the medical necessity for the item and substantiates the answers on the CMN (if applicable) . . . or information on a supplier prepared statement or physician attestation (if applicable). . . . The patient's medical record is not limited to the physician's office records. It may include hospital, nursing home, or HHA records and records from other health care professionals. *CMS Pub. 100-08, Ch. 5, §5.7.*

Medicare Program Integrity Manual, Pub. 100-08 ("CMS Pub. 100-08"), Ch. 13, §13.5.1 explains the reasonable and necessary provisions in LCDs as follows:

> Contractors shall describe in the draft LCD the circumstances under which the item or service is reasonable and necessary under 1862(a)(1)(A). Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:
>
> - Safe and effective;
> - Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary); and
> - Appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is:
>   - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
>   - Furnished in a setting appropriate to the patient's medical needs and condition;
>   - Ordered and furnished by qualified personnel;
>   - One that meets, but does not exceed, the patient's medical need; and
>   - At least as beneficial as an existing and available medically appropriate alternative.

I have given substantial deference to the Centers for Medicare and Medicaid Services (CMS) manuals implementing the Medicare program, which are of persuasive importance and instructive and influential. Specific to the instant case is the Medicare Benefit Policy Manual, Publication 100-2, Chapter 15, Covered and Other Health Services, §110 Durable Medical Equipment; and the Medicare Claims Processing Manual, Publication 100-4, Chapter 20, Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS). *See also* CFR §405.1062.

Analysis

I have reviewed the criteria necessary for Medicare coverage of tumor treatment field therapy, established in accordance with the statutory and regulatory provisions of Part B of Title XVIII of the Social Security Act, and I have determined that the services at issue met such criteria. For the reasons set forth below, I find that the tumor treatment field therapy administered to the appellant on the dates of service at issue was medically reasonable and necessary.

In this appeal, Ms. Noonan (Parrish Law Firm) and Mr. Timothy Parks (Novocure) testified as to the pertinent medical facts concerning this Beneficiary. Ms. Noonan indicated additional appeals were submitted by the Parish Law firm and from the supplier. In reference to the facts, the following was noted:

> Mr. Parks spoke to the Beneficiary and as of April 10, 2019, the Beneficiary is stable and is doing quite well. Her response to treatment is impressive. Beneficiary was listed as a 33-year-old female and clinical condition was determined on February 14, 2014. MRI showed large left cystic temporal illness. On February 25, 2016, she underwent a left craniotomy, which confirmed her condition was that of glioblastoma. In May 2016, she completed chemotherapy and radiation with concurrent temodar. On June 16, 2016, she started Optune TTFields. In April 2017, she completed 12 cycles of temodar and continued with TTFields. MRIs have remained stable with no progression. On March 2018- March 2019, she has been stable. In December 2018, her tumor was shown to have reduced in size. Her ECOG/WHO score was listed as "0" meaning she was able to carry on all predisease performance without restriction. Her Karnofsky Performance score was an 80% with indicated the Beneficiary could carry on normal activity and to work.

REVIEW OF THE DEVICE AND REGULATIONS

Medicare is a defined benefit program, which means that it does not cover all available medical services and supplies.[4] Instead, Medicare coverage is limited to those medical services and supplies identified by Congress, by the Secretary of Health and Human Services, and by CMS in implementing Congressional directives. For example, Medicare does not cover medical services that are experimental or investigational.[5]

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[4] *Consultants in Pain Medicine, P.A.* (December 2014). In general, although MAC decisions have no precedential value, the decisions may serve as a guidepost to disposition of similar cases. 70 Fed. Reg. 11420, 11449 (Mar. 8, 2005); *see also Vidant Medical Center,* (MAC March 2014).

[5] *See also* Medicare Program Integrity Manual, Publication 100-08, Chapter 13, §13.5.1.

OPTUNE DEVICE

The TTFT Optune device (E0766) is a portable, wearable medical device that produces alternating electrical fields, tumor treating field ("TTFields") within the brain by means of electrically insulated surface transducer arrays placed on the scalp. The TTFields disrupt the rapid cell division exhibited by cancer cells supporting tumor growth inhibition without damage to normal neuronal function or structure or any systemic toxicity.

FDA CLEARANCE

At the hearing, Ms. Noonan argued that the FDA approved, through its more rigorous review process, a device to deliver TTFT, finding it to be safe and effective for the treatment of glioblastomas. In support of her argument, the Parrish Law Firm submitted a letter generated by the Center for Devices and Radiological Health of the FDA on October 5, 2015, which states in pertinent part as follows:

> This device is indicated as a treatment for adult patients (22 years or older) with histologically confirmed glioblastoma multiforme (GBM). Optune™ (formerly the NovoTTF-100A System) with Temozolomide is indicated for treatment of adult patients with newly diagnosed, supratentorial glioblastoma following maximal debulking surgery and completion of radiation together with concomitant standard of care chemotherapy. (Exhibit 5)

At the outset, I find that FDA clearance of a device is not synonymous with Medicare coverage.[6] The regulations state that "CMS *may consider* for Medicare coverage" FDA approved devices "that have been categorized as non-experimental/investigational."[7] The regulations further clarify that CMS uses FDA categorization *"as a factor"* in making coverage decisions. [8] Thus, under Medicare regulations, the fact that a device, Optune™, may be deemed non-experimental by virtue of its FDA classification means, as a threshold matter, only that it is eligible to be considered for Medicare coverage. [9]

This conclusion is further reinforced by the statements published by CMS and the FDA in the Federal Register explaining the difference between CMS review of a medical device as compared to reviews conducted by the FDA for pre-market approval.[10] Specifically, each process operates under different statutory standards and asks different questions to meet its respective mandates. [11] Moreover, CMS serves a different function by providing health insurance to protect the nation's aged and disabled. Under §1862(a)(1) of the Act, CMS makes determinations regarding the coverage of specific items and services. In short, CMS must decide: "what items and services it can and should pay for; how it should accomplish the payment; and how much to pay."[12] Thus, FDA clearance of an item or service does not preclude CMS or its contractors, in analyzing whether a particular item or service is medically reasonable and necessary, from making an independent inquiry into whether the item or service is safe and effective and not experimental or investigational.[13] Nor does it preclude CMS or its contractors from inquiring whether the

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[6] *In the Case of Vision Quest Industries, Inc.,* (MAC June 2012).
[7] *See* 42 C.F.R. §405.201(a)(2).
[8] *See* 42 C.F.R. §405.201(a)(1).
[9] *In the Case of Vision Quest Industries, Inc.,* (MAC June 2012).
[10] *See* 68 Fed. Reg. 55634 (Sept. 26, 2003); *See also* 75 Fed. Ref. 57045.
[11] *Id.; See also* MPIM, Publication 100-08, Chapter 13, §5.1.
[12] *In the Case of Vision Quest Industries, Inc.,* (MAC June 2012).
[13] *Id.*

item or service is supported by *"[p]ublished authoritative evidence derived from definitive randomized clinical trials or other definitive studies."*[14]

Therefore, although Optune™ received FDA approval or clearance for treatment of newly diagnosed glioblastoma multiforme, the appellant's medical condition, I find that such FDA approval/clearance alone does not generally entitle a device to Medicare coverage. Accordingly, I find that FDA clearance for Optune™ by itself does not establish that the device meets Medicare coverage requirements; i.e., that it has been shown to be a medically reasonable and necessary treatment for treatment of newly diagnosed glioblastoma multiforme.

NCCN GUIDELINES

Ms. Noonan further argued that TTFT for glioblastoma is included in the National Comprehensive Cancer Network ("CNNC") guidelines and is considered the standard of care for newly diagnosed glioblastoma.

> **THE NATIONAL COMPREHENSIVE** Cancer Network (NCCN) has updated its Clinical Practice Guidelines in Oncology for Central Nervous System Cancers (NCCN Guidelines®) to recommend alternating electric field therapy (also known as tumor-treating fields, Optune) in combination with temozolomide as a category 1 treatment for patients with newly diagnosed glioblastoma. The NCCN panel members made this recommendation in conjunction with Temozolomide after maximal safe resection and completion of radiation therapy.
>
> The updated recommendation follows the publication of a phase III trial that demonstrated improvement in 5-year survival results with the combination therapy in *The Journal of the American Medical Association.*[1] The study showed the combination therapy significantly improved survival outcomes compared with Temozolomide alone.
>
> More than 1,800 patients with glioblastoma are receiving therapy with tumor-treating fields as of December 31, 2017, and more than 7,000 patients with glioblastoma have received such treatment to date. Physicians at more than 700 cancer centers in the United States, and at more than 1,100 medical institutions globally, have been certified to prescribe this radiation therapy to patients with newly diagnosed and recurrent glioblastoma.
>
> **More on Therapy With Tumor-Treating Fields**
>
> THERAPY WITH tumor-treating fields is intended as a treatment for adult patients 22 years of age or older with histologically confirmed glioblastoma multiforme. In combination with Temozolomide, it is indicated for the treatment of adult patients with newly diagnosed, supratentorial glioblastoma following maximal debulking surgery and completion of radiation therapy together with concomitant standard-of-care chemotherapy.[15] https://www.ascopost.com/issues/april-25-2018/updated-nccn-guidelines-for-newly-diagnosed-glioblastoma/

[14] *Consultants in Pain Medicine, P.A.* (December 2014); *In the Case of Vision Quest Industries, Inc.,* (MAC June 2012).
[15] Effect of tumor-treating fields plus maintenance Temozolomide vs maintenance Temozolomide alone on survival in patients with glioblastoma. JAMA 318:2306-2316, 2017.

> Nearly all studies showed a significant negative relationship between advancing age and duration of postoperative survival.8–18 In a 2005 report of a study by Korshunov et al,18 the percentage of patients younger than age 40 years who survived more than five years was 34%, compared with 6% for patients age 40 years old and older. The researchers suggested age 40 years as the most appropriate cutoff for dividing patients with GB into groups according to prognosis. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3037140/

The applicable NCCN guidelines further state that all recommendations are category 2A unless otherwise indicated.. It is undisputed that the FDA approved Optune™ for treatment of newly diagnosed glioblastoma multiforme, the appellant's medical condition. Moreover, the NCCN guidelines recommend treatment of methylated glioblastoma with the use alternative electric field therapy. Such recognition is Category 2A, which establishes that "based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate."[16] "The MBPM guidelines at 50.4.5.B[17] specifically state that, for purposes of the NCCN, a use will be medically accepted if the indication is a Category 1 or Category 2A designation.

PEER REVIEW LITERATURE

The appellant contends that the NovoTTF 100-A System is reasonable and necessary and not investigational or experimental based on clinical studies, abstracts and publications. In making a determination as to whether the NovoTTF-100A System is reasonable and necessary, i.e., safe and effective, and not experimental or investigational, only evidence that was in existence on or before the dates of service at issue is relevant. The appellant must prove that the NovoTTF-100A System was medically reasonable and necessary when the service was furnished.

The Appellant has submitted documentation confirming that the Optune device received an initial April 2011 FDA pre-market approval and later October 2015 FDA pre-market approval supplement. Additional studies and literature have been submitted pertaining to the efficacy of tumor treating fields therapy for indications stated in those FDA approvals, including use of the Optune Device for treatment of recurrent Glioblastoma which has not responded to standard therapy (per the April 2011 FDA approval) and for treatment of newly diagnosed Glioblastoma (per the October 2015 FDA approval supplement). (*See* CD attachment at Exhibit 5).

Appellant submitted additional and relevant material in support of his appeal such as the article from the Journal of the American Medical Association (JAMA) titled Maintenance Therapy with Tumor-Treating Fields Plus Temozolomide Vs. Ternozolomide Alone for Glioblastoma — A Randomized Clinical Trial. The article describes the superior results in progression free survival as well as overall survival of glioblastoma patients using TTFields. This trial shows that the Optune device was safe, non-investigational and effective. Moreover, this trial shows that the Optune device was appropriate for this individual Enrollee's needs, specifically the treatment of newly discovered glioblastoma.

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[16] *See https://www.nccn.org/professionals/physician_gls/categories_of_consensus.aspx* (last visited on 2/5/2019).

[17] In note that the aforementioned Medicare Manual provision refers to drugs and biological, not durable medical equipment; however, I find that it clearly explains the NCCN category designations, which apply to this case.

Additional material submitted by the Beneficiary also shows the medical community generally accepts the use of TTFT. In the 2016 version of the National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology Central Nervous System Cancers guidelines, alternating electric field therapy is a treatment option suggested for glioblastoma: This suggestion was found in a treatment guideline from a national cancer organization, not evidence based on an individual physician treating a single patient in a clinical setting.

Applicable Medicare Regulations: LCD L34823

In this case, as in all Medicare appeals, the appellant has the burden to establish that she is entitled to Medicare payment. The regulations are clear that it is the responsibility of the supplier to furnish sufficient information to determine whether payment is due and the amount of payment.[18] The governing LCD clearly states that "**tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.**" At the hearing, Ms. Noonan argued that the LCD was not applicable because it had not been updated since 2013 and that the DME MAC medical director had indicated that "the policy did not apply to newly diagnosed glioblastoma." In support of her argument, Ms. Parrish submitted a letter from CGS Administrators, LLC, which was addressed to Novocure and states in pertinent part as follows:

> The DME MAC Medical Directors received your June 20, 2018, e-mail to Dr. Robert Hoover requesting a formal reconsideration of the TTFT Local Coverage Determination (LCD) coverage criteria.
>
> Currently, the TTFT LCD includes language indicating that the coverage of TTFT for recurrent glioblastoma multiforme (GMB) is not reasonable and necessary. Coverage for newly diagnosed GBM is not addressed. Your letter asks that we revise the LCD to allow coverage for recurrent GBM and add coverage for newly diagnosed GBM.

Proposed changes to LCD DL34823--On May 9, 2019, The Centers for Medicare and Medicaid Services (CMS) assigned to the Durable Medical Equipment Medicare Administrative Contractors (DME MACs) the task of developing Local Coverage Determinations (LCDs) for Durable Medical Equipment, Prostheses; Orthoses, and Supplies (DMEPOS). The DME MACs are proposing a revision to the **Tumor Treatment Field Therapy (TTFT LCD L34823)** to cover newly diagnosed glioblastoma multiforme (GBM).

An ALJ is not bound by contractor LCDs or CMS program guidance, such as program memoranda and manual instructions, "but will give substantial deference to these policies if they are applicable to a particular case." 42 C.F.R. § 405.1062(a). An ALJ must explain the reason for not following such a policy in a specific case. 42 C.F.R. § 405.1062(b). Any decision to disregard a policy "applies only to the specific claim being considered and does not have precedential effect." (Id.)

Based upon the facts of this case, and giving appropriate deference to the LCD policy guidance, I decline to follow the LCD in this case, and instead find that the Optune device will be considered reasonable and necessary as specifically applied to the Beneficiary's diagnosis and treatment regimen. In declining to follow the pertinent LCD, I have considered the following criteria, as suggested by Medicare manual

[18] *See* §1833(e) of the Social Security Act; 42 C.F.R. §424.5(a)(6).

guidance: (1) whether the device can be expected to make a meaningful contribution to the treatment of the patient's illness or injury or to the improvement of his or her malformed body member; (2) whether the device can be considered a reasonable treatment, considering expense versus therapeutic benefits, comparative cost of feasible alternatives, and whether the device serves the same purpose as other available equipment or alternatives; (3) whether all features of the device are required for treatment of the Beneficiary's condition; and, (4) the period of time the DME will be considered medically necessary, which is generally based on the physician's estimate of the time that his or her patient will need the equipment. *CMS Pub. 100-02, Ch. 15, §110.1(c).*

Moreover, the LCD, as currently published does not cite any studies, articles or other sources for this determination, or specify any specific diagnoses for which the treatment will be considered as not reasonable and necessary. It makes no distinction between recurrent glioblastoma or newly discovered glioblastoma, and the lack of sources or information on which the determination was based makes it unascertainable. In addition, no reference is made in the LCD Sources of Information and Basis for Decision to several of the more recent studies and guidelines, including the more recent pivotal study and resulting October 2015 FDA pre-market approval supplement allowing the Optune device to be used for newly diagnosed GBM, and the additional even more recent literature and established guidelines supporting such use. NCCN Guidelines for Anaplastic Gliomas/Glioblastoma for 2017 and 2018 category of evidence 2A (based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate), the Mayo Clinic's information on Glioblastoma, and the fact that numerous commercial insurers cover the treatment.[19] (List of commercial insurers that cover TTFT in CD).

Applying the aforementioned criteria, a review of the medical record clearly demonstrates that the Appellant is a 34 year-old woman who is being treated for newly diagnosed, glioblastoma and has undergone debulking as well as total resection, followed by adjuvant TMZ treatment. Additionally, her physician documented that her KPS scale score was 80% and her Echo score was 0. Consequently, after a careful and thorough review of Appellant's arguments and the evidence in the record, the I find the use of the Optune device for an FDA approved indication can be expected to make a meaningful contribution to the treatment of Appellant's glioblastoma. In fact, the treatment was and is being provided under the supervision of an oncology specialist. The physician recommended treatment with the Optune device to halt the progression of her disease, which has proven successful. Mr. Timothy Parks testified to and the MRI supports that the Beneficiary had no appreciable evidence of worsening residual or recurrent lesion. Lastly proposed LCD changes to DL34823 show that two Contractors: Noridian and CGS have looked to allow coverage to newly diagnosed glioblastoma patients and the Beneficiary meets the criteria for coverage.

The undersigned understands Medicare often times lags behind other insurers in covering new medical technologies but it is unreasonable to deny Medicare coverage to this beneficiary in view of the extensive literature, favorable clinical trials, national adoption by other health plans and applicable NCCN Guidelines support. Therefore, the record supports the claimed Optune device treatment was safe and effective and clinically appropriate. Accordingly, the device is reasonable and necessary for the treatment of Appellant's glioblastoma.

[19] Glioblastoma, Mayo Clinic, *see* https://www.mayoclinic.org/diseases-conditions/glioblastoma/cdc-20350148

CONCLUSIONS OF LAW

The Appellant's use of the Optune device, HCPCs Code E0766, during dates of service meets requirements for Medicare Part B DME coverage because the device is shown to: meet the definition of durable medical equipment, to have been reasonable and necessary for the treatment of the Beneficiary's GBM, and to have been for use in the Beneficiary's home. *See Sections 1832(a)(1), 1834(a)(13), 1861(n),(s)(6), 1862(a)(1)(A) of Title XVIII 42 C.F.R. §410.38(a); CMS Pub. 100-02, Ch. 15, §110 et seq..*

ORDER

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED.

Dated: JUN 27 2019

Lissette M. Figueroa
U.S. Administrative Law Judge